

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

THE CITY OF HUNTINGTON,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

Civil Action No. 3:17-01362
Hon. David A. Faber

CABELL COUNTY COMMISSION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

Civil Action No. 3:17-01665
Hon. David A. Faber

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' *DAUBERT* MOTION TO
EXCLUDE THE OPINIONS OF JAMES E. RAFALSKI**

TABLE OF CONTENTS

I. INTRODUCTION 1

II. MR. RAFALSKI’S BACKGROUND, OPINIONS, AND METHODOLOGIES 2

 A. Mr. Rafalski’s Background..... 2

 B. Mr. Rafalski’s Six Methods and Suspicious Order “Flagging” Exercise. 3

III. LEGAL STANDARD..... 5

IV. ARGUMENT..... 7

 A. Mr. Rafalski’s Testimony Should Be Excluded Because His Flagging
 Methods Are Not Reliable. 7

 B. Mr. Rafalski’s Testimony Should Be Excluded Because He Has No
 Methodology or Basis To Claim that Orders Flagged by His Unreliable
 Methodologies Were Actually Diverted. 12

 C. Mr. Rafalski’s Testimony Should Be Excluded Because His Analysis Is
 “Result-Driven.” 16

V. CONCLUSION..... 17

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Cooper v. Smith & Nephew, Inc.</i> , 259 F.3d 194 (4th Cir. 2001)	1, 5, 6, 16
<i>Daubert v. Merrell Dow Pharm., Inc.</i> , 43 F.3d 1311 (9th Cir. 1995)	12
<i>Daubert v. Merrell Dow Pharm., Inc.</i> , 509 U.S. 579 (1993)	6
<i>In re Fed. Home Loan Mortg. Corp. (Freddie Mac) Sec. Litig.</i> , 218 F.R.D. 174 (S.D.N.Y. 2012)	10
<i>In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.</i> , 892 F.3d 624 (4th Cir. 2018)	6, 15, 17
<i>Marsh v. W.R. Grace & Co.</i> , 80 F. App'x 883 (4th Cir. 2003)	12
<i>Masters Pharmaceutical, Inc. v. Drug Enforcement Admin.</i> , 861 F.3d 206 (D.C. Cir. 2017)	7
<i>Mike's Train House, Inc. v. Lionel, LLC</i> , 472 F.3d 398 (6th Cir. 2006)	12
<i>Nease v. Ford Motor Co.</i> , 848 F.3d 219 (4th Cir. 2017)	6
<i>Phelan v. Synthes (U.S.A.)</i> , 35 F. App'x 102 (4th Cir. 2002)	10
<i>Ruffin v. Shaw Indus., Inc.</i> , 149 F.3d 294 (4th Cir. 1998)	12
<i>UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres</i> , 949 F.3d 825 (3d Cir. 2020)	6, 7
<i>Wehling v. Sandoz Pharm. Corp.</i> , 162 F.3d 1158, 1998 WL 546097 (4th Cir. 1998)	12
Statutes	
SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894	15

Rules

Federal Rule of Evidence 702.....5

I. INTRODUCTION

The Court should exclude the opinions of James Rafalski, Plaintiffs’ purported expert on Defendants’ suspicious order monitoring systems.¹ In an effort to “quantify” the number of orders of prescription opioids for Huntington and Cabell County that purportedly should have been blocked by Distributors, Mr. Rafalski uses an unreliable “flagging” exercise created solely for purposes of litigation. Mr. Rafalski claims that his made-for-litigation methods are tied to real-world monitoring practices, but just weeks ago, another of Plaintiffs’ experts responsible for writing the computer code for the methods admitted that Mr. Rafalski’s methods were nothing more than “*stylized illustrations*” of what happens in the real world.² In addition to using an unreliable flagging exercise, Mr. Rafalski failed to review relevant evidence, including the West Virginia Board of Pharmacy due diligence files that, he admits, would have been “important” for his assessments of Defendants’ suspicious order monitoring systems.

Mr. Rafalski compounds the unreliability of his flagging opinions by taking them a step further and using them to claim that nearly every order shipped into Cabell County and Huntington was “likely to be diverted.”³ This is nothing but mere *ipse dixit*.⁴ Mr. Rafalski readily admits that he did none of the work necessary to support such an outlandish claim, and he admitted that no one else has ever attempted his alchemy of transforming means of detecting

¹ James Rafalski was the subject of a *Daubert* motion filed in Track 1 of the MDL. In Track 1, Judge Polster granted Defendants’ motion to exclude Mr. Rafalski’s legal opinions but otherwise allowed his testimony. *See* Ex. 1 (Opinion and Order Regarding Defendants’ Motions to Exclude Opinions of James Rafalski and Craig McCann, 17-md-2804). Since then, Mr. Rafalski’s opinions have become even more extreme (going from identifying orders meriting further review to orders “likely to be diverted”), just as *newly developed evidence since Track 1* shows his opinions to lack any methodological basis.

² Ex. 2 (McCann Dep., Sept. 1, 2020) at 125:2-6.

³ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 250:8-12; 284:24-285:20; Ex. 4 (Rafalski Rep.) at 51.

⁴ *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001).

orders that exceed a threshold into a means of reliably identifying that the orders will be diverted. It therefore comes as no surprise that Mr. Rafalski's opinions are contrary to both DEA's own diversion estimates (well under 1% of total orders) and the testimony of DEA's former head of the Office of Diversion Control before Congress that less than 1% of prescribers are illegally prescribing. The gap between Mr. Rafalski's results and DEA's own diversion estimates is itself an indicia of unreliability. Even worse, Mr. Rafalski makes his outlandish claim that nearly every order flagged is "likely to be diverted" even though, as he admitted, he never looked at a single order that was flagged, he could not identify a single order that should have been blocked, and he could not identify a single order that was actually diverted.

Mr. Rafalski's use of a flagging exercise with no grounding in the real world, his unsupported claims based on that exercise, and his failure to review key evidence render his opinions unreliable and inadmissible. This Court should exercise its role as gatekeeper and preclude Mr. Rafalski from testifying at trial.

II. MR. RAFALSKI'S BACKGROUND, OPINIONS, AND METHODOLOGIES

A. Mr. Rafalski's Background.

After a 26-year career as a police officer in Detroit, Michigan, Mr. Rafalski joined the Detroit field office of DEA as a Diversion Investigator in 2004.⁵ He retired from DEA in 2017.⁶

Although Mr. Rafalski "received training" on suspicious order monitoring and participated in an investigation of a registrant for failure to design and operate an adequate suspicious order monitoring system,⁷ he admits there has not been "any time in [his] career

⁵ Ex. 4 (Rafalski Rep.) at 4.

⁶ *Id.*

⁷ *Id.* at 7.

where [he has] ever had occasion to design or operate a suspicious order monitoring system.”⁸

Mr. Rafalski further admits he has never “been hired by anyone to implement a suspicious order monitoring system.”⁹

B. Mr. Rafalski’s Six Methods and Suspicious Order “Flagging” Exercise.

In an effort to “quantify” the number of prescription opioid orders that Defendants purportedly should have refused to ship to Huntington and Cabell County, Mr. Rafalski created a suspicious order flagging exercise using “six suspicious order methodologies.”¹⁰ The six methods are:

- A. Maximum Monthly, Trailing Six-Month Threshold
- B. Trailing Six-Month Maximum Monthly, Fixed After First Triggered Threshold
- C. Twice Trailing Twelve-Month Average
- D. Three Times Trailing Twelve-Month Average
- E. Maximum 8,000 Dosage Units Monthly
- F. Maximum Daily Dosage Units.¹¹

⁸ Ex. 5 (Rafalski Dep., Feb. 7, 2020) at 45:17-21.

⁹ *Id.* at 45:13-16.

¹⁰ Ex. 4 (Rafalski Rep.) at 47.

¹¹ *Id.* at 47-50. In his previous expert reports submitted in the opioid litigation matters in Track 1 and New York, Mr. Rafalski’s flagging exercise included only five methodologies—A and C through F. Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 138:20-22. Mr. Rafalski created Method B for the first time in this case because he was interested in running Method A without his due diligence assumption—“once an order by a pharmacy is flagged and the distributor does not conduct sufficient due diligence to dispel the suspicion of diversion, each subsequent order by that pharmacy is also flagged.” *Id.* at 138:23-139:10; Ex. 4 (Rafalski Rep.) at 47. Method B is the same as Method A except it does not include the due diligence assumption. Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 137:18-20.

Mr. Rafalski rejected four of his six methods as unusable for detecting suspicious orders.¹² He considered only two methods—Method A (Maximum Monthly, Trailing Six-Month Threshold) and Method B (Trailing Six-Month Maximum Monthly, Fixed After First Triggered Threshold)—to be “plausible.”¹³ Mr. Rafalski purported to base Methods A and B on a system peculiar to one distributor, Masters Pharmaceutical, that is not a defendant in this litigation.¹⁴ But Mr. Rafalski admitted that Methods A and B did not actually follow the operating procedures used by the Masters suspicious order monitoring (“SOMS”) program.¹⁵

Mr. Rafalski admitted that his flagging methodology involved drawing extreme conclusions based on the simple fact of a pharmacy exceeding its threshold in a given month. For example, he admitted that, if a pharmacy ordered a single pill bottle above the highest level in the last six months, he would flag it and treat it as illegitimate.¹⁶

For five of these methods—all but Method B—Mr. Rafalski applied a further “due diligence assumption,” namely that once there was a first flagged order, he treated every subsequent order as suspicious on the assumption that Defendants conducted no review of customer orders.¹⁷ In other words, for five of these methods, there was only an initial order flagged by the methodology, and then every other order was flagged as “suspicious” on the

¹² Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 131:10-13 (testifying that he “would not use” Methods C through F).

¹³ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 131:5-9; *see also* Ex. 4 (Rafalski Rep.) at 50.

¹⁴ Ex. 4 (Rafalski Rep.) at 50.

¹⁵ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 121:23-122:6; *see also id.* at 148:11-22, 151:24-152:10 (noting differences between Methods A and B and the actual Masters SOMS program).

¹⁶ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 159:8-13.

¹⁷ Ex. 4 (Rafalski Rep.) at 47; *see also* Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 99:2-8.

assumption that there was no due diligence done after the initial order.¹⁸ Only Method B does not apply this assumption.¹⁹ Mr. Rafalski (or Plaintiffs' counsel) created this due diligence assumption out of whole cloth.²⁰ Nor could Mr. Rafalski point to any Defendant registrant that uses this assumption in flagging suspicious orders.

After applying the six methods to detect allegedly suspicious orders, Mr. Rafalski concluded that it was “more likely than not” that the allegedly suspicious orders identified by the flagging exercise were actually diverted.²¹ He thus estimated that close to 90% of the orders shipped into Huntington and Cabell County—“tens of millions of orders”—were “more likely than not” diverted.²²

III. LEGAL STANDARD

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is qualified and his testimony will be (1) helpful to the trier of fact; (2) “based on sufficient facts or data”; and (3) the product of “reliable principles and methods” that (4) have been “reliably applied . . . to the facts of the case.” Fed. R. Evid. 702. Because “expert witnesses have the potential to be both powerful and quite misleading,” the district court must act as a gatekeeper. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). The court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper*, 259 F.3d at 199 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993)).

To determine whether an expert's testimony is reliable, the court analyzes several factors

¹⁸ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 105:15-106:9.

¹⁹ Ex. 4 (Rafalski Rep.) at 47.

²⁰ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 92:22-93:3, 93:16-94:4.

²¹ Ex. 4 (Rafalski Rep.) at 51; Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 250:8-12, 284:24-285:20.

²² Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 284:24-285:20; *see also* Ex. 4 (Rafalski Rep.) at 48-50.

outlined by the Supreme Court in *Daubert*. Those factors include whether the expert’s theory has been tested; whether it has been subjected to peer review and publication; whether it has a high known or potential rate of error; whether there are standards controlling its operation; and whether it has achieved “general acceptance” within the relevant scientific community. *Cooper*, 259 F.3d at 199 (citing *Daubert*, 509 U.S. at 592-94). “[A] known technique which has been able to attract only minimal support with the community may properly be viewed with skepticism.” *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) (quoting *Daubert*, 509 U.S. at 594).

In the Fourth Circuit, an expert’s opinion may be rejected as unreliable if it is “connected to existing data only by the *ipse dixit* of the expert.” *Cooper*, 259 F.3d at 203 (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 157 (1999)). An opinion may also be rejected if it is based on “[r]esult-driven analysis” or “cherry-picking” of relevant data, which constitute “a quintessential example of applying methodologies (valid or otherwise) in an unreliable fashion.” *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 892 F.3d 624, 634 (4th Cir. 2018).

“[T]he objective of *Daubert*’s gatekeeping requirement is to ‘make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.’” *Cooper*, 259 F.3d at 201 (quoting *Kumho Tire*, 526 U.S. at 152). “[G]iven the potential persuasiveness of expert testimony, proffered evidence that has a greater potential to mislead than to enlighten should be excluded.” *In re Lipitor*, 892 F.3d at 632.

Even in the bench trial context, where a judge rather than a jury sits as the factfinder, Rule 702 plays an important role in the consideration of expert testimony. *See UGI Sunbury*

LLC v. A Permanent Easement for 1.7575 Acres, 949 F.3d 825, 832-33 (3d Cir. 2020)

(recognizing that “Rule 702 applies whether the trier of fact is a judge or a jury,” and noting that “the failure to conduct any form of ‘assessment’ of an expert and the proposed testimony before admitting the testimony is an abuse of discretion”).

IV. ARGUMENT

A. Mr. Rafalski’s Testimony Should Be Excluded Because His Flagging Methods Are Not Reliable.

By his own account, only two of Mr. Rafalski’s methods for identifying problematic, or “flagged,” orders shipped into Huntington and Cabell County by Defendants are even “plausible.”²³ But neither of these two methods are generally accepted or reliable, and Mr. Rafalski should be precluded from testifying about them at trial.

As an initial matter, Mr. Rafalski rejected four of his six methodologies—Methods C, D, E, and F—as unusable for flagging orders.²⁴ Mr. Rafalski’s other two methodologies—Method A and Method B (which is based on Method A)—were purportedly drawn from the court’s decision in *Masters Pharmaceutical, Inc. v. Drug Enforcement Admin.*, 861 F.3d 206 (D.C. Cir. 2017).²⁵ But Mr. Rafalski admitted that Method A, and therefore, Method B, is not generally accepted by anyone:

Q. Is there any general acceptance you can point me to for Method A with its due diligence assumption?

A. Acceptance by –

²³ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 131:5-9.

²⁴ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 131:10-13.

²⁵ Ex. 4 (Rafalski Rep.) at 50.

Q. Anyone, distributors, regulators, academics?

A. *No, sir.*²⁶

The DEA has never employed Methods A and B or any of Mr. Rafalski's other methods²⁷—and neither has he outside of this litigation.²⁸ Indeed, during a recent *Frye* hearing in New York, Mr. Rafalski admitted that there is no single, generally accepted method that manufacturers and distributors must apply to define and detect suspicious orders.²⁹ Rather, according to Mr. Rafalski, suspicious order monitoring systems must be designed on a company-by-company basis, and there is no generally accepted set of requirements that must be met:

“There’s no one-size-fits-all suspicious order monitoring system.”³⁰

Mr. Rafalski attempted to justify Methods A and B by claiming that they were endorsed in the D.C. Circuit's *Masters* decision, but Mr. Rafalski conceded that his methodologies deviated from both the decision in *Masters* and the suspicious order monitoring program in use by Masters Pharmaceutical. This is because Mr. Rafalski did not perform the Method A and B

²⁶ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 140:5-11 (emphasis added).

²⁷ See Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 139:15-18 (“Q. Are you aware of anyone at DEA who ever ran the Masters methodology when you were at the DEA to any set of data? A. No, sir.”); Ex. 6 (Aug. 18 *Frye* Tr.) at 20:3-9 (“Q. . . . Am I correct that while you were at the DEA, the DEA never analyzed ARCOS data using the methodologies that Dr. McCann presented and you also presented in your report? A. That exact specific scenario, no, sir.”). See also Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 139:19-24 (“Q. Are you aware of any company or regulator who has ever run Masters Exhibit A with the due diligence assumption to any set of data in the history of the world? A. No, sir. Not at least up to when I left my employment.”).

²⁸ See Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 139:11-14 (“Q. Are you aware -- did you ever run the Masters methodology when you were at the DEA to any set of data. A. No, sir.”); see also Ex. 6 (Aug. 18 *Frye* Tr.) at 20:10-12 (“Q. You never used those methodologies, correct? A. No, sir.”).

²⁹ Ex. 6 (Aug. 18 *Frye* Tr.) at 6:7-7:4, 8:3-18.

³⁰ *Id.* at 8:3-5, 9:14-10:17, 11:10-14.

calculations himself.³¹ Instead, he relied on another one of Plaintiffs' experts, Dr. McCann, to do the calculations, without ever checking Dr. McCann's work or discussing the assumptions that Dr. McCann independently made in his *Masters* methodologies.³²

This disconnect between the two experts is critical. Dr. McCann testified that, for his part, he has no expertise in suspicious order monitoring, no opinion whether any of Mr. Rafalski's flagging methods are appropriate for identifying suspicious orders—much less whether they are generally accepted for that purpose—and no opinion that any of the flagged orders were actually suspicious.³³ But, Mr. Rafalski and Dr. McCann never even discussed Mr. Rafalski's flagging methodologies to make sure Dr. McCann had an understanding of how any of them should be applied.³⁴ Mr. Rafalski did not speak to Dr. McCann about the analysis until August 29, nearly a month after Mr. Rafalski submitted his Track 2 report.³⁵ Mr. Rafalski admitted that he reached out to Dr. McCann because he needed “clarification” on how Dr. McCann had performed his calculations, specifically for the *Masters* methodologies.³⁶ Mr. Rafalski had no idea whether he even agreed with the unguided judgment calls Dr. McCann had

³¹ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 85:9-11.

³² Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 85:9-18; *id.* at 306:24-307:9 (“Q. Okay. Tell me the ten assumptions he made in coming up with his code that he testified about under oath. A. I do not know all ten; no, sir.”); *see also* Ex. 6 (Aug. 18 *Frye* Tr.) at 61:18-22 (“Q. Okay. Do you know what the 5 to 10 decisions he had to make to be able to perform his Method A calculation that you relied on? Do you know what those 5 to 10 decisions were? A No, sir.”); Ex. 7 (Aug. 19 *Frye* Tr.) at 117:22-25 (McCann admitting that he never asked Rafalski to check his work).

³³ Ex. 2 (McCann Dep., Sept. 1, 2020) at 13:11-13, 14:1-15:4; Ex. 7 (Aug. 19 *Frye* Tr.) at 91:22-24, 92:25-93:12, 97:9-16, 163:25-164:3.

³⁴ Ex. 7 (Aug. 19 *Frye* Tr.) at 114:15-18 (McCann admitting he “never talked to Mr. Rafalski to get an understanding of how the . . . flagging methods were supposed to be applied”).

³⁵ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 85:19-87:16; *see also* Ex. 2 (McCann Dep., Sept. 1, 2020) at 17:9-20:13 (admitting that he first discussed his efforts to implement *Masters* with Rafalski a few days before the deposition).

³⁶ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 86:19-87:16.

to make in deciding which orders to flag.³⁷ Instead, he simply took Dr. McCann’s calculations and plugged them into his report “word for word and number for number,” without scrutinizing them or fully understanding them.³⁸

Mr. Rafalski’s blind adoption of calculations that he did not fully understand left Mr. Rafalski unable to meet the Court’s standards for allowing expert testimony. The Fourth Circuit has recognized that expert opinions should be excluded if the trial court determines that “there is simply too great an analytical gap between the data and the opinion proffered.” *Phelan v. Synthes (U.S.A.)*, 35 F. App’x 102, 107 (4th Cir. 2002) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). Mr. Rafalski admitted that, because he did not fully understand the decisions Dr. McCann made in running his methods, he could not say “how far of a gap there is” between Dr. McCann’s output and Mr. Rafalski’s opinions about that output.³⁹

In fact, Methods A and B differ from the methodology employed by the *Masters* court in at least two important respects. First, Mr. Rafalski makes the incorrect and unsupported assumption under Method A (but not Method B) that any time a single order (no matter how small) by a single pharmacy was flagged, ***all*** subsequent orders placed by the same pharmacy were also flagged under the ***untested assumption*** that no due diligence was ever conducted by Distributors. As an initial matter, DEA admitted that it does not require distributors to hold all

³⁷ Ex. 6 (Aug. 18 *Frye* Tr.) at 59:16-24; *id.* at 60:12-61:10.

³⁸ Ex. 6 (Aug. 18 *Frye* Tr.) at 58:10-19. At least one other court has deemed Dr. McCann’s methods of analyzing large data sets unreliable. *See In re Fed. Home Loan Mortg. Corp. (Freddie Mac) Sec. Litig.*, 218 F.R.D. 174, 181-82 (S.D.N.Y. 2012); *see also* Ex. 7 (Aug. 19 *Frye* Tr.) at 122:8-123:6 (discussing the opinion in the *Freddie Mac Securities Litigation* excluding Dr. McCann’s testimony as “internally inconsistent,” “unpersuasive,” and “unreliable”).

³⁹ Ex. 6 (Aug. 18 *Frye* Tr.) at 61:23-62:5.

subsequent orders from a pharmacy when a single order is flagged.⁴⁰ And Plaintiffs’ counsel conceded as much when they reached out to DEA last week and asked DEA to change sworn testimony given under oath about this issue.⁴¹ Further, as Mr. Rafalski admitted, neither Masters Pharmaceutical nor the court in the *Masters* decision “use[d] the due diligence assumption” that he employed in this litigation.⁴² Unsurprisingly, eliminating that untested assumption resulted in dramatically lower numbers of flagged orders.⁴³

Second, as Mr. Rafalski and Dr. McCann admitted, Methods A and B do not follow the operating procedures of Masters’ Suspicious Order Monitoring program manual.⁴⁴ Instead, according to Dr. McCann, the flagging methods are “*stylized illustrations* suggested by the underlying documents that you have identified, not attempting [sic] to implement these documents precisely.”⁴⁵

⁴⁰ See Ex. 8 (Prevoznik Dep., May 17, 2019) at 1238:6-20. Recognizing the absence of evidence to support Mr. Rafalski’s “due diligence assumption,” Plaintiffs’ counsel just recently wrote a letter to DEA asking it to rewrite adverse deposition testimony on this issue from over a year ago. See Ex. 9 (Letter from L. Singer to DOJ). Defendants believe Plaintiffs’ attempt to manufacture evidence is wholly improper and contrary to the record.

⁴¹ See Ex. 9 (Letter from L. Singer to DOJ).

⁴² Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 134:3-5 (admitting that *Masters* does not “use the due diligence assumption” in Method A); Ex. 2 (McCann Dep., Sept. 1, 2020) at 104:22-105:2 (admitting that *Masters* does not “describe the assumption” that he used in Method A).

⁴³ Ex. 4 (Rafalski Rep.) at 49.

⁴⁴ Ex. 2 (McCann Dep., Sept. 1, 2020) at 115:16-23 (Method A “does not follow what we have read here in the operating procedures for the SOMS program described in the Masters Pharmaceutical Comprehensive Compliance Policy Manual”); *id.* at 119:1-7 (Method B “does not follow the operating procedures of the SOMS program described in the Masters Pharmaceutical Comprehensive Compliance Policy Manual”); Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 148:11-22 (agreeing that “what Method A and Method B do is different than Masters” because they were based on a calendar month calculation instead of a rolling 30-days calculation); *id.* at 151:24-152:10 (noting that another deviation between Methodology B and the *Masters* system is that Masters did not lock in the first six months as the perpetual threshold).

⁴⁵ Ex. 2 (McCann Dep., Sept. 1, 2020) at 125:2-6.

An expert opinion is unreliable and inadmissible where the expert relied on methodologies that are not generally accepted in the field and were, instead, created for litigation. *See, e.g., Marsh v. W.R. Grace & Co.*, 80 F. App'x 883, 887-88 (4th Cir. 2003) (excluding an expert's testimony where his methods were "not generally accepted by the medical community"); *Ruffin v. Shaw Indus., Inc.*, 149 F.3d 294, 299 (4th Cir. 1998) (ruling expert testimony inadmissible where the test used by the expert was "not generally accepted in the relevant scientific community"); *Wehling v. Sandoz Pharm. Corp.*, 162 F.3d 1158, 1998 WL 546097, at *3 (4th Cir. 1998) (noting that "[a]nother significant fact weighing against admitting the testimony is where, as here, the expert developed his opinions expressly for the purposes of testifying"). With no grounding in *Masters* and no endorsement by DEA, industry practice, or any other expert, the invented-for-litigation flagging methods used by Mr. Rafalski are not admissible.⁴⁶

B. Mr. Rafalski's Testimony Should Be Excluded Because He Has No Methodology or Basis To Claim that Orders Flagged by His Unreliable Methodologies Were Actually Diverted.

The Court also should reject Mr. Rafalski's opinion that nearly every lawfully written prescription in Huntington and Cabell County was diverted.⁴⁷ Mr. Rafalski's opinion is

⁴⁶ *See id.*; *see also Mike's Train House, Inc. v. Lionel, LLC*, 472 F.3d 398, 408 (6th Cir. 2006) (courts are properly "suspicious of methodologies created for the purpose of litigation, because 'expert witnesses are not necessarily always unbiased scientists.'" (quoting *Turpin v. Merrell Dow Pharm., Inc.*, 959 F.2d 1349, 1352 (6th Cir. 1992))); *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (holding that a "very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying").

⁴⁷ *See* Ex. 4 (Rafalski Rep.) at 48-49, 51 (flagging close to 90% of Defendants' orders shipped into Huntington and Cabell County and claiming that "the pills identified in Methodology A and B were more likely than not diverted and used for an illicit purpose"); Ex. 3 (Rafalski Dep., Sept.

contradicted by his report and deposition testimony and is wholly unsupported.⁴⁸ Thus, there is too great an analytical gap between his arbitrary flagging methods and his unsupported claim that the flagged orders were “more likely than not” diverted. It is mere “*ipse dixit*.”

Mr. Rafalski admitted that he did not do even the most basic work to link his flagging methods to actual diversion:

- He did not review the due diligence files for his flagged orders to see if they appeared legitimate.⁴⁹
- He did not determine how many orders were actually investigated and cleared by Defendants.⁵⁰
- He failed to review or evaluate any of the flagged orders themselves to determine whether they were actually suspicious.⁵¹
- He failed to form an opinion on how much prescribing is legitimate, so that he could test his “likely to be diverted” claim.⁵²
- He ignored changes in medical practice that increased legitimate opioid prescribing.⁵³
- He failed to evaluate how many of his flagged orders actually “went to fill legitimate medical need.”⁵⁴

11, 2020) at 250:8-12, 284:24-285:20 (claiming that “all of the millions” of Defendants’ orders identified by Method A were “more likely than not” diverted).

⁴⁸ Compare, e.g., Ex. 4 (Rafalski Rep.) at 51 (claiming that the pills flagged by Methods A and B were “more likely than not” diverted), with Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 100:3-7 (admitting he does not know “what percentage of these tens of millions of orders . . . actually went to fill legitimate medical need”).

⁴⁹ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 91:16-19, 92:22-93:3, 93:16-94:4.

⁵⁰ *Id.* at 99:9-17.

⁵¹ *Id.* at 87:21-88:5, 88:12-15, 91:10-15.

⁵² Ex. 6 (Aug. 18 *Frye* Tr.) at 23:21-24:5.

⁵³ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 299:19-300:4.

⁵⁴ *Id.* at 100:3-7, 101:2-5.

- He even admitted that he does not know if any of the flagged orders were actually diverted.⁵⁵

Rafalski's only basis for his remarkable claim that *nearly every pharmacy's pills* were "likely to be diverted" was his "due diligence assumption"—that once there was a first flagged order, every subsequent order should be treated as suspicious (even if the order exceeded the highest ordering level from the prior six months by just *one single pill bottle in just one single month*).⁵⁶

But even Rafalski admits that, no matter what acceptability his flagging method has for identifying *suspicious* orders, this flagging method has no real-world support as a basis for identifying *diverted* orders. No one at DEA or elsewhere has used his methods to estimate the level of diversion.

Q. . . . DEA has never conducted that exercise that you're aware of, have they?

A. No, not that I am aware of.⁵⁷

* * *

Q. . . . Can you point me to any time you're aware of when anyone has used Method A to try to estimate, not flagged orders, not even suspicious orders, but actually diverted orders? Yes or no.

A. No.⁵⁸

⁵⁵ Ex. 6 (Aug. 18 *Frye* Tr.) at 42:7-15 ("Q. . . . Do you know if any of the orders that were flagged by Dr. McCann's methodology that you adopted, do you know if any of those orders were actually diverted? A. When you say the word 'actually,' I have to answer that no, sir. Q. You don't know? A. No, sir.").

⁵⁶ See Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 159:8-13 (one bottle extra would flag); *id.* at 105:15-106:9 (every subsequent order flags).

⁵⁷ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 297:9-12.

⁵⁸ Ex. 6 (Aug. 18 *Frye* Tr.) at 33:7-13.

Indeed, he stated that it would not be a “valid exercise” for the DEA to use Method A to identify orders that were likely to be diverted.⁵⁹ And, at the New York *Frye* hearing, he directly conceded that Method A is not a generally accepted methodology for identifying diverted orders:

Q. *Is it generally accepted?* Is there any measure of general acceptance you can point me to for using Method A to estimate, not flagged orders, not suspicious orders, but actually diverted orders, as you have done in your testimony?

A. **No.**⁶⁰

DEA does use a generally accepted methodology for identifying diverted orders.⁶¹ But Mr. Rafalski’s simplistic flagging methods bear no relationship to DEA’s methodology, which generates diversion estimates that are exponentially lower (well under 1% of total orders),⁶² or the Congressional testimony of DEA’s former head of the Office of Diversion Control that less than 1% of prescribers are illegally prescribing.⁶³ DEA’s results are far more realistic than Mr. Rafalski’s estimate that 90% of opioids shipped to Huntington and Cabell County are likely diverted to drug seekers. *See In re Lipitor*, 892 F.3d at 637-38 (affirming the district court’s exclusion of expert’s analysis “squarely at odds with the conclusions of a published, peer-reviewed study” where the “expert offers an unpersuasive rationale for why the [published]

⁵⁹ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 297:1-8.

⁶⁰ Ex. 6 (Aug. 18 *Frye* Tr.) at 33:14-19.

⁶¹ Ex. 6 (Aug. 18 *Frye* Tr.) at 33:20-23. *See also* SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894.

⁶² Ex. 6 (Aug. 18 *Frye* Tr.) at 38:25-39:4.

⁶³ Ex. 10 (Testimony of Joseph Rannazzisi, House Hearing on Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014)) at 76 (“Mr. Rannazzisi: I think that if you are talking about 99.5 percent of the prescribers, no, they are not overprescribing, but our focus is in rogue pain clinics and rogue doctors who are overprescribing. Actually, they are prescribing illegally, they are not overprescribing, they are illegally prescribing.”).

findings are wrong and his correct”). The fact that Mr. Rafalski’s results deviate so significantly from DEA’s own diversion estimates is itself an indicia of unreliability.

As noted, the Fourth Circuit routinely rejects expert opinions connected to the expert’s methodology “only by the *ipse dixit* of the expert.” *Cooper*, 259 F.3d at 203. Because Mr. Rafalski has no basis to connect his flagging methods with his incredible claim that nearly every order shipped to Huntington and Cabell County was diverted, his opinion that all flagged orders were “more likely than not” diverted should be excluded.

C. Mr. Rafalski’s Testimony Should Be Excluded Because His Analysis Is “Result-Driven.”

The Court also should also exclude Mr. Rafalski’s opinions because Mr. Rafalski ignored key evidence on distributors and pharmacies in West Virginia undermining his theory that Defendants failed to maintain effective controls against diversion.

Significantly, Mr. Rafalski did not review any documents or testimony from the West Virginia Board of Pharmacy (“WV BOP”), the agency in West Virginia that licenses and monitors distributors and pharmacies.⁶⁴ Despite acknowledging that they would be relevant to his opinions, Mr. Rafalski did not look into the standards that the WV BOP applies when permitting distributors to distribute prescription opioids in West Virginia, or the WV BOP’s findings regarding the Defendants.⁶⁵ Having failed to learn about the role of the WV BOP, Mr. Rafalski did not know that the WV BOP considers a distributor’s “maintenance of effective controls against diversion” before issuing or renewing any license to distribute controlled

⁶⁴ Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 31:21-32:5, 32:17-24, 33:1-3.

⁶⁵ *Id.* at 44:21-46:1, 46:23-47:16.

substances in the state of West Virginia.⁶⁶ He did not know that the WV BOP determines that a distributor was compliant with the laws regarding wholesale drug distribution each time it issues a license.⁶⁷

Nor did Mr. Rafalski look into the WV BOP's monitoring of pharmacies in West Virginia. He did not know that WV BOP inspectors physically inspect each pharmacy in West Virginia every one to two years and write detailed reports of their inspections.⁶⁸ And he failed to review any Board of Pharmacy inspection records for the West Virginia pharmacies discussed in his report, even though he testified they "could be relevant" to assessing those pharmacies.⁶⁹

Courts consistently exclude "result-driven" expert analysis that cherry picks relevant data and fails to account for contrary evidence. *In re Lipitor*, 892 F.3d at 634. Mr. Rafalski's result-driven analysis of Defendants' compliance programs, which ignored relevant evidence from the West Virginia Board of Pharmacy, should be excluded.

V. CONCLUSION

For the foregoing reasons, the Court should exclude Mr. Rafalski's opinions.

⁶⁶ See Ex. 3 (Rafalski Dep., Sept. 11, 2020) at 45:5-13.

⁶⁷ See *id.*

⁶⁸ *Id.* at 33:14-24, 35:2-5.

⁶⁹ *Id.* at 34:1-11.

Dated: October 2, 2020

Respectfully submitted,

/s/ Timothy C. Hester

Timothy C. Hester (DC 370707)
Laura Flahive Wu
Andrew P. Stanner
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001
Tel: (202) 662-5324
thester@cov.com
lflahivewu@cov.com
astanner@cov.com

/s/ Paul W. Schmidt

Paul W. Schmidt
COVINGTON & BURLING LLP
The New York Times Building
620 Eighth Avenue
New York, New York 10018
Tel: (212) 841-1000
pschmidt@cov.com

/s/ Jeffrey M. Wakefield

Jeffrey M. Wakefield (WVSB #3894)
jwakefield@flahertylegal.com
Jason L. Holliday (WVSB #12749)
jholliday@flahertylegal.com
FLAHERTY SENSABAUGH BONASSO PLLC
P.O. Box. 3843
Charleston, WV 25338-3843
Telephone: (304) 345-0200

Counsel for McKesson Corporation

/s/ Gretchen M. Callas

Gretchen M. Callas (WVSB #7136)
JACKSON KELLY PLLC
Post Office Box 553
Charleston, WV 25322
Tel: (304) 340-1000
Fax: (304) 340-1050
gcallas@jacksonkelly.com

/s/ Robert A. Nicholas

Robert A. Nicholas
Shannon E. McClure
REED SMITH LLP
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, PA 19103
Tel: (215) 851-8100
Fax: (215) 851-1420
rnicholas@reedsmith.com
smcclure@reedsmith.com

Counsel for AmerisourceBergen Drug Corporation

/s/ Steven R. Ruby

Michael W. Carey (WVSB No. 635)
Steven R. Ruby (WVSB No. 10752)
David R. Pogue (WVSB No. 10806)
Raymond S. Franks II (WVSB No. 6523)
CAREY DOUGLAS KESSLER & RUBY PLLC
901 Chase Tower, 707 Virginia Street, East
P.O. Box 913
Charleston, WV 25323
Telephone: (304) 345-1234
Facsimile: (304) 342-1105
mwcarey@csdlawfirm.com
sruby@cdkrlaw.com
drpogue@cdkrlaw.com
rsfranks@cdkrlaw.com

/s/ Enu Mainigi

Enu Mainigi
F. Lane Heard III
Ashley W. Hardin
Jennifer G. Wicht
WILLIAMS & CONNOLLY LLP
725 Twelfth Street NW
Washington, DC 20005
Tel: (202) 434-5000
Fax: (202) 434-5029
emainigi@wc.com
lheard@wc.com
ahardin@wc.com
jwicht@wc.com

Counsel for Cardinal Health, Inc.

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on October 2, 2020, the foregoing *Memorandum of Law in Support of Defendants' Daubert Motion to Exclude the Opinions of James E. Rafalski* was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

Dated: October 2, 2020

/s/ Timothy C. Hester
Timothy C. Hester